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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

IN RE:	:	
Fosamax Products Liability Litigation	:	1:06-md-1789 (JFK)
	:	
This Document Relates to:	:	**ANSWER AND AFFIRMATIVE**
Vivian C. Wood	:	**DEFENSES OF MERCK**
v. Merck & Co., Inc.	:	**& CO., INC.;**
	:	**DEMAND FOR JURY TRIAL**
Case No: 1: 07-cv-6981-JFK	:	

Defendant, Merck Co., Inc. ("Merck"), by and through its undersigned attorneys, hereby answers the Complaint. Merck denies all allegations set forth in the Complaint except to the extent such allegations are specifically admitted below:

I. JURISDICTION AND VENUE

1. The allegations of the first sentence of Paragraph 1 are conclusions of law to which no response is required. To the extent that a response is required, Merck denies each and every allegation of the first sentence of Paragraph 1. As to the allegations of the second sentence of Paragraph 1, Merck is without knowledge or information sufficient to form a belief as to these allegations, except that Merck admits that it is a corporation organized under the laws of the State of New Jersey with its principal place of business in New Jersey. Merck is without knowledge as to the allegations in the third sentence of

Paragraph 1, but for jurisdictional purposes only, admits that Plaintiff seeks in excess of $75,000.

2. The allegations of Paragraph 2 are conclusions of law to which no response is required. To the extent a response is required, Merck denies the allegations of Paragraph 2, except that Merck admits that pursuant to Section 4 of Case Management Order No. 3 entered by Judge John F. Keenan on November 1, 2006, this action may be filed directly in the Southern District of New York. Merck reserves all rights under Section 4 of Case Management Order No. 3 and respectfully refers the Court to the relevant Case Management Order.

3. The allegations of Paragraph 3 are conclusions of law to which no response is required. To the extent a response is required, Merck denies the allegations of Paragraph 3, except that Merck admits that pursuant to Section 4 of Case Management Order No. 3 entered by Judge John F. Keenan on November 1, 2006, this action may be filed directly in the Southern District of New York. Merck reserves all rights under Case Management Order No. 3 and respectfully refers the Court to the relevant Case Management Order.

II. PARTIES

4. Merck denies each and every allegation of Paragraph 4, except Merck states that it is without knowledge as to the Plaintiff's residence or the dates on which she alleges she used FOSAMAX®.

5. Merck admits that Plaintiff brings this action seeking damages and other relief, but denies that there is any legal or factual basis for same.

6. Merck admits the allegations of Paragraph 6.

7. Merck admits that service in this case was accomplished by serving CT Corporation at 111 Eighth Avenue, New York, New York 10011. Merck denies all remaining allegations of Paragraph 7.

8. Merck admits that it is registered to do business in the State of Georgia.

9. Merck is without knowledge as to what is meant by the phrase "regularly transacted," so the allegations in Paragraph 9 are denied.

10. Merck denies each and every allegation of Paragraph 10, except that it admits that Merck manufactured, marketed, and distributed the prescription medicine FOSAMAX® in accordance with its approved prescribing information. Merck denies any allegations in Paragraph 10 inconsistent with that prescribing information and respectfully refers the Court to the Physicians' Desk Reference ("PDR") for FOSAMAX® for its actual language and full text.

11. Merck admits only that it distributed FOSAMAX® for prescription in accordance with its approved prescribing information and denies any allegations in Paragraph 11 inconsistent with that prescribing information. Merck respectfully refers the Court to the PDR for FOSAMAX® for its actual language and full text. Except as expressly admitted herein, Merck denies the remaining allegations of Paragraph 11.

12. Merck denies the allegations of the first sentence of Paragraph 12, except admits that it distributed FOSAMAX® for prescription in accordance with its approved prescribing information. Merck denies all remaining allegations of Paragraph 12.

III. FACTUAL BACKGROUND

13. Merck denies each and every allegation of Paragraph 13, except that Merck admits that it sought and, in 1995, first obtained FDA approval to manufacture and

market FOSAMAX® 10 mg and FOSAMAX® 40 mg tablets, a prescription medication approved by the FDA for prescription in accordance with its approved prescribing information. Merck denies any allegations in Paragraph 13 inconsistent with that prescribing information.

14. Merck admits only that FOSAMAX® is a prescription medication approved by the FDA for prescription in accordance with its approved prescribing information and that Merck manufactured, marketed, and distributed the prescription medicine FOSAMAX® in accordance with its approved prescribing information. Merck denies any allegations in Paragraph 14 inconsistent with that prescribing information, and denies all remaining allegations of Paragraph 14.

15. Merck denies each and every allegation of Paragraph 15, except that Merck admits that Fosamax product sales in 2006 amounted to approximately $3.13 billion and that Fosamax has been prescribed to and benefited millions of patients.

16. Merck admits only that FOSAMAX® is a prescription medication approved by the FDA for prescription in accordance with its approved prescribing information and denies any allegations in Paragraph 16 inconsistent with that prescribing information. Merck also refers the Court to the prescribing information for Aredia and Zometa, and denies any allegations in Paragraph 16 with respect to Aredia and Zometa inconsistent with that prescribing information.

17. Merck admits only that some bisphosphonates contain nitrogen and some do not and that FOSAMAX® is a prescription medication approved by the FDA for prescription in accordance with its approved prescribing information. Merck denies any allegations in Paragraph 17 inconsistent with that prescribing information. Merck

respectfully refers the Court to the PDR for FOSAMAX® for its actual language and full text. Merck also refers the Court to the prescribing information for Aredia and Zometa, and denies any allegations in Paragraph 17 with respect to Aredia and Zomenta inconsistent with that prescribing information. Merck denies the remaining allegations of Paragraph 17.

18. Merck denies each and every allegation of Paragraph 18.

19. Merck denies each and every allegation of Paragraph 19.

20. Merck denies each and every allegation of Paragraph 20.

21. Merck admits the allegations of the first sentence of Paragraph 21. Merck denies all remaining allegations of Paragraph 21.

22. Merck denies each and every allegation of Paragraph 22.

23. Merck denies each and every allegation of Paragraph 23.

24. Merck denies each and every allegation of Paragraph 24, except that Merck admits upon information and belief that the FDA prepared an internal "ODS Postmarketing Safety Review" with respect to intravenous bisphosphonates in late 2003, but further states on information and belief that this review was not made available to persons outside of the FDA until March 2005, and Merck respectfully refers the Court to said document for its actual language and full text.

25. Merck denies each and every allegation of Paragraph 25.

26. Merck denies each and every allegation of Paragraph 26.

27. Merck denies each and every allegation of Paragraph 27, except that Merck admits upon information and belief that the FDA prepared an internal "ODS Postmarketing Safety Review" with respect to intravenous bisphosphonates in late 2003,

and later prepared a second review in 2005 to also include information concerning two oral bisphosphonates, but further states upon information and belief that neither of these reviews were made available to persons outside of the FDA until March 2005, and Merck respectfully refers the Court to said documents for their actual language and full text.

28. Merck denies each and every allegation of Paragraph 28, and Merck respectfully refers the Court to the referenced Post Marketing Safety Review for its actual language and full text.

29. Merck denies each and every allegation of Paragraph 29, except that Merck admits that on January 31, 2005, it received a request dated January 24, 2005 from the FDA to update the label for FOSAMAX® to include bisphosphonate class labeling for ONJ. Merck submitted a draft revised label to the FDA on March 1, 2005. FDA comments on this draft revised label were received in June 2005, and the new label was made publicly available in July 2005.

30. Merck denies each and every allegation of Paragraph 30.

31. Merck denies each and every allegation of Paragraph 31.

32. Merck denies each and every allegation of Paragraph 32.

33. Merck denies each and every allegation of Paragraph 33.

34. Merck is without knowledge as to whether Plaintiff was prescribed FOSAMAX® and the manner in which she used FOSAMAX®. Merck denies the remaining allegations in Paragraph 34.

35. Merck denies each and every allegation of Paragraph 35.

COUNTS

COUNT 1: NEGLIGENCE

36. Merck repleads its answers to Paragraphs 1 through and including 35, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

37. The allegations in Paragraph 37 are conclusions of law to which no response is required; to the extent that a response is deemed necessary, the allegations are denied and Merck respectfully refers the Court to the relevant legal standard, including any conflict of law rules.

38. Merck denies each and every allegation of Paragraph 38.

39. Merck denies each and every allegation of Paragraph 39, including each and every allegation contained in subparts (a) through (i).

40. Merck denies each and every allegation of Paragraph 40.

41. Merck denies each and every allegation of Paragraph 41.

42. Merck denies each and every allegation of Paragraph 42.

43. Merck denies each and every allegation of Paragraph 43.

44. Merck denies each and every allegation of Paragraph 44.

COUNT 2: STRICT LIABILITY – DESIGN DEFECT

45. Merck repleads its answers to Paragraphs 1 through and including 44, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

46. Merck denies each and every allegation of Paragraph 46, except that it admits that Merck manufactured the prescription medicine FOSAMAX® for prescription in accordance with its approved prescribing information.

47. Merck denies each and every allegation of Paragraph 47, except that it admits that Merck marketed and distributed the prescription medicine FOSAMAX® for prescription in accordance with its approved prescribing information.

48. Merck is without knowledge or information sufficient to form a belief as to the allegations of Paragraph 48.

49. Merck is without knowledge or information sufficient to form a belief as to the allegations of Paragraph 49.

50. Merck is without knowledge or information sufficient to form a belief as to the allegations of Paragraph 50.

51. Merck is without knowledge or information sufficient to form a belief as to the allegations of Paragraph 51.

52. Merck denies each and every allegation of Paragraph 52.

53. Merck denies each and every allegation of Paragraph 53.

54. Merck denies each and every allegation of Paragraph 54.

55. Merck denies each and every allegation of Paragraph 55.

56. Merck denies each and every allegation of Paragraph 56.

57. Merck denies each and every allegation of Paragraph 57.

COUNT 3: STRICT LIABILITY – MARKETING DEFECT – FAILURE TO WARN

58. Merck repleads its answers to Paragraphs 1 through and including 57, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

59. Merck denies each and every allegation of Paragraph 59, except that it admits that Merck manufactured the prescription medicine FOSAMAX® for prescription in accordance with its approved prescribing information.

60. Merck denies each and every allegation of Paragraph 60, except that it admits that Merck marketed and distributed the prescription medicine FOSAMAX® for prescription in accordance with its approved prescribing information.

61. Merck is without knowledge or information sufficient to form a belief as to the allegations of Paragraph 61.

62. Merck is without knowledge or information sufficient to form a belief as to the allegations of Paragraph 62.

63. Merck is without knowledge or information sufficient to form a belief as to the allegations of Paragraph 63.

64. Merck is without knowledge or information sufficient to form a belief as to the allegations of Paragraph 64.

65. Merck denies each and every allegation of Paragraph 65.

66. Merck denies each and every allegation of Paragraph 66.

67. Merck denies each and every allegation of Paragraph 67.

68. Merck denies each and every allegation of Paragraph 68.

69. Merck denies each and every allegation of Paragraph 69.

70. Merck denies each and every allegation of Paragraph 70.

71. Merck denies each and every allegation of Paragraph 71.

72. Merck denies each and every allegation of Paragraph 72, including each and every allegation of subparagraphs (a) – (c).

73. Merck denies each and every allegation of Paragraph 73.

74. Merck denies each and every allegation of Paragraph 74.

75. Merck denies each and every allegation of Paragraph 75.

COUNT 4: BREACH OF EXPRESS WARRANTY

76. Merck repleads its answers to Paragraphs 1 through and including 75, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

77. Merck denies each and every allegation of Paragraph 77, and respectfully refers the Court to the FDA-approved prescribing information for any and all representations contained therein. Merck further avers that FOSAMAX® is a prescription medication approved by the FDA for prescription in accordance with its approved prescribing information.

78. Merck denies each and every allegation of Paragraph 78.

79. Merck denies each and every allegation of Paragraph 79.

80. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 80.

81. Merck denies each and every allegation of Paragraph 81.

82. Merck denies each and every allegation of Paragraph 82.

COUNT 5: BREACH OF IMPLIED WARRANTY

83. Merck repleads its answers to Paragraphs 1 through and including 82, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

84. Merck denies each and every allegation of Paragraph 84, except that Merck admits that it manufactured, marketed, and distributed the prescription medicine FOSAMAX® for prescription in accordance with its approved prescribing information.

85. Merck denies each and every allegation of Paragraph 85, and respectfully refers the Court to the FDA-approved prescribing information for any and all representations contained therein. Merck further avers that FOSAMAX® is a prescription medication approved by the FDA for prescription in accordance with its approved prescribing information.

86. Merck denies each and every allegation of the first sentence of Paragraph 86. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of the second sentence of Paragraph 86.

87. Merck denies each and every allegation of Paragraph 87.

88. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 88.

89. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 89.

90. Merck denies each and every allegation of Paragraph 90.

91. Merck denies each and every allegation of Paragraph 91.

COUNT 6: FRAUDULENT MISREPRESENTATION

92. Merck repleads its answers to Paragraphs 1 through and including 91, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

93. Merck denies each and every allegation of Paragraph 93, including each and every allegation contained in subparts (a) and (b).

94. Merck denies each and every allegation of Paragraph 94.

95. Merck denies each and every allegation of Paragraph 95.

96. Merck denies each and every allegation of Paragraph 96.

97. Merck denies each and every allegation of Paragraph 97.

98. Merck denies each and every allegation of Paragraph 98.

99. Merck denies each and every allegation of Paragraph 99.

100. Merck denies each and every allegation of Paragraph 100.

COUNT 7: FRAUDULENT CONCEALMENT

101. Merck repleads its answers to Paragraphs 1 through and including 100, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

102. Merck denies each and every allegation of Paragraph 102, including each and every allegation contained in subparts (a) and (b).

103. Merck denies each and every allegation of Paragraph 103.

104. Merck denies each and every allegation of Paragraph 104.

105. Merck denies each and every allegation of Paragraph 105.

106. Merck denies each and every allegation of Paragraph 106.

107. Merck denies each and every allegation of Paragraph 107.

108. Merck denies each and every allegation of Paragraph 108.

COUNT 8: PUNITIVE DAMAGES

109. Merck repleads its answers to Paragraphs 1 through and including 108, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

110. Merck denies each and every allegation of Paragraph 110.

111. Merck denies each and every allegation of Paragraph 111, except that it admits that Merck received several letters from the FDA's Division of Drug Marketing, Advertising and Communications ("DDMAC") regarding FOSAMAX® and that Merck responded to the letters to the FDA's satisfaction.

112. Merck denies each and every allegation of Paragraph 112.

113. Merck denies each and every allegation of Paragraph 113, except that it admits that DDMAC sent Merck a letter in August 1997 regarding FOSAMAX® and that Merck responded to the letter to the FDA's satisfaction.

114. Merck denies each and every allegation of Paragraph 114, except that Merck admits that it received correspondence from DDMAC in 1999 regarding FOSAMAX® and that Merck responded to the correspondence to the FDA's satisfaction.

115. Merck denies each and every allegation of Paragraph 115, except that Merck admits that DDMAC sent Merck a letter in 2001 regarding Merck's web site for FOSAMAX® and that Merck responded to the letter to the FDA's satisfaction.

116. Merck denies each and every allegation of Paragraph 116.

117. Merck denies each and every allegation of Paragraph 117.

118. Merck denies each and every allegation of Paragraph 118, except that Merck admits upon information and belief that the FDA prepared an internal "ODS Postmarketing Safety Review" with respect to intravenous bisphosphonates in late 2003, but further states on information and belief that this review was not made available to persons outside of the FDA until March 2005, and Merck respectfully refers the Court to said document for its actual language and full text.

119. Merck denies each and every allegation of Paragraph 119, except that Merck admits upon information and belief that the FDA prepared an internal "ODS Postmarketing Safety Review" with respect to intravenous bisphosphonates in late 2003, and later prepared a second review in 2005 to also include information concerning two oral bisphosphonates, but further states upon information and belief that neither of these reviews were made available to persons outside of the FDA until March 2005, and Merck respectfully refers the Court to said documents for their actual language and full text.

120. Merck denies each and every allegation of Paragraph 120.

121. Merck denies each and every allegation of Paragraph 121.

122. Merck denies each and every allegation of Paragraph 122, except that it admits that Merck scientists participated in the VIGOR study involving VIOXX® ("Vioxx"), published in the New England Journal of Medicine, and respectfully refers the Court to the referenced study for its actual conclusions and full text.

123. Merck denies each and every allegation of Paragraph 123, except that it admits that Merck received a letter from Thomas W. Abrams of DDMAC in September 2001 and respectfully refers the Court to that letter for its actual language and full text.

124. Merck denies each and every allegation of Paragraph 124.

125. Merck denies each and every allegation of Paragraph 125, except that it admits that on August 26, 2004, Merck issued a press release regarding the conclusions of a study presented at the 20th International Conference of Pharmacoepideminology & Therapeutic Risk Management and respectfully refers the Court to that press release for its actual language and full text.

126. Merck denies each and every allegation of Paragraph 126, except that it admits that the referenced study exists and respectfully refers the Court to said study for its actual language and full text. Merck further admits that on September 30, 2004, Merck announced that in a prospective, randomized, placebo-controlled clinical trial there was an increased relative risk for confirmed cardiovascular events beginning after 18 months of treatment in the patients taking Vioxx compared with those taking placebo, and that, given the availability of alternative therapies and questions raised by the data from that trial, Merck concluded that a voluntary withdrawal of Vioxx best served the interests of patients.

127. Merck denies each and every allegation of Paragraph 127.

128. Merck denies each and every allegation of Paragraph 128.

V. DAMAGES

129. Merck repleads its answers to Paragraphs 1 through and including 128, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

130. Merck denies each and every allegation of Paragraph 130.

131. Merck denies each and every allegation of Paragraph 131.

132. Merck denies each and every allegation of Paragraph 132.

133. Merck denies each and every allegation of Paragraph 133.

VI. DEMAND FOR JURY TRIAL

134. The allegations of Paragraph 134 do not require a response.

VII. PRAYER

Merck denies that Plaintiff is entitled to any of the relief requested in her Global Prayer for Relief.

WHEREFORE, Merck respectfully demands judgment dismissing Plaintiff's Complaint with prejudice and awarding Merck such other and further relief that the Court may deem just and proper.

AFFIRMATIVE DEFENSES

Discovery and investigation may reveal that any one or more of the following affirmative defenses should be available to Merck in this matter. Merck, therefore, asserts said affirmative defenses in order to preserve the right to assert them. Upon completion of discovery, and if the facts warrant, Merck may withdraw any of these affirmative defenses as may be appropriate. Further, Merck reserves the right to amend its Answer to assert additional defenses, cross-claims, counterclaims, and other claims and defenses as discovery proceeds. Further answering and by way of additional defense, Merck states as follows:

FIRST AFFIRMATIVE DEFENSE

Each and every claim asserted or raised in the Complaint is barred by the applicable statute of limitations and is otherwise untimely.

SECOND AFFIRMATIVE DEFENSE

The Complaint fails to state a claim upon which relief can be granted.

THIRD AFFIRMATIVE DEFENSE

Each and every claim asserted or raised in the Complaint is barred by the doctrines of estoppel, waiver or statutory and regulatory compliance.

FOURTH AFFIRMATIVE DEFENSE

If Plaintiff has sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries or losses were caused in whole or in part through the operation of nature or other intervening cause or causes.

FIFTH AFFIRMATIVE DEFENSE

To the extent that Plaintiff asserts claims based on Merck's adherence to and compliance with applicable state laws, regulations and rules, such claims are preempted by federal law under the Supremacy Clause of the United States Constitution.

SIXTH AFFIRMATIVE DEFENSE

To the extent that Plaintiff asserts claims based upon an alleged failure by Merck to warn Plaintiff directly of alleged dangers associated with the use of FOSAMAX®, such claims are barred under the learned intermediary doctrine because Merck has discharged its duty to warn in its warnings to the prescribing physician.

SEVENTH AFFIRMATIVE DEFENSE

If Plaintiff has sustained injuries or losses as alleged in the Complaint, such injuries or losses were cause in whole or in part by the contributory negligence of the allegedly injured Plaintiff.

EIGHTH AFFIRMATIVE DEFENSE

Any liability that might otherwise be imposed upon this Defendant is subject to reduction by the application of the doctrine of comparative fault and/or negligence.

NINTH AFFIRMATIVE DEFENSE

If Plaintiff has sustained injuries or losses as alleged in the Complaint, such injuries or losses were only sustained after Plaintiff knowingly, voluntarily, and willfully assumed the risk of any injury as the result of the consumption of, administration of, or exposure to any medicine or pharmaceutical preparation manufactured or distributed by Merck or other manufacturer.

TENTH AFFIRMATIVE DEFENSE

If Plaintiff has sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were caused by the actions of persons not having real or apparent authority to take said actions on behalf of Merck and over whom Merck had no control and for whom Merck may not be held accountable.

ELEVENTH AFFIRMATIVE DEFENSE

If Plaintiff has sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were proximately caused by Plaintiff's misuse or abuse of FOSAMAX®.

TWELFTH AFFIRMATIVE DEFENSE

If Plaintiff has sustained injuries or losses as alleged in the Complaint, such injuries or losses resulted from Plaintiff's pre-existing and/or unrelated medical, genetic and/or environmental conditions, diseases, or illnesses, idiosyncratic reactions, subsequent medical conditions or natural courses of conditions for which this Defendant is not responsible.

THIRTEENTH AFFIRMATIVE DEFENSE

To the extent that Plaintiff relies upon any theory of breach of warranty, such claims are also barred for lack of timely notice of breach and/or lack of privity.

FOURTEENTH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred in whole or in part under the applicable state law because FOSAMAX® was subject to and received pre-market approval by the FDA under 52 Stat. 1040, 21 U.S.C. § 301.

FIFTEENTH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred in whole or in part because the product at issue was made in accordance with the state of the art at the time it was manufactured.

SIXTEENTH AFFIRMATIVE DEFENSE

To the extent that Plaintiff seeks punitive damages for the conduct which allegedly caused the injuries asserted in the Complaint, such an award would, if granted, violate Merck's state and federal constitutional rights.

SEVENTEENTH AFFIRMATIVE DEFENSE

To the extent that Plaintiff seeks punitive damages for an alleged act or omission of Merck, no act or omission was malicious, willful, wanton, reckless or grossly negligent and, therefore, any award of punitive damages is barred.

EIGHTEENTH AFFIRMATIVE DEFENSE

To the extent that Plaintiff seeks punitive damages, such claim is barred because FOSAMAX® and its labeling was subject to and received pre-market approval by the FDA under 52 Stat. 1040, 21 U.S.C. § 301.

NINETEENTH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred in whole or in part under comment k to Section 402A of the Restatement (Second) of Torts.

TWENTIETH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred in whole or in part because Merck provided legally adequate "directions or warnings" as to the use of FOSAMAX® and any other medicine or pharmaceutical preparation Plaintiff alleges to have taken within the meaning of comment j to Section 402A of the Restatement (Second) of Torts.

TWENTY-FIRST AFFIRMATIVE DEFENSE

Plaintiff's claims are barred under Section 4, *et seq.*, of the Restatement (Third) of Torts: Products Liability.

TWENTY-SECOND AFFIRMATIVE DEFENSE

Plaintiff's claims are barred under comment f to Section 6 of the Restatement (Third) of Torts: Products Liability.

TWENTY-THIRD AFFIRMATIVE DEFENSE

There is no practical or technically feasible alternative design that would have reduced the alleged risk without substantially impairing the reasonably anticipated and intended function of FOSAMAX®.

TWENTY-FOURTH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred in whole or in part by failure to mitigate damages.

TWENTY-FIFTH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred in whole or in part because Merck's conduct conforms with medical knowledge.

TWENTY-SIXTH AFFIRMATIVE DEFENSE

With respect to each and every cause of action, Plaintiff is not entitled to recovery for strict liability because Plaintiff cannot state claims founded in strict liability because, among other things, comments j and k to Section 402A of the Restatement (Second) of Torts relegates Plaintiff's claims to a negligence cause of action.

TWENTY-SEVENTH AFFIRMATIVE DEFENSE

All activities of Merck as alleged in the Complaint were expressly authorized and/or regulated by a government agency. Therefore, Plaintiff's claims pertaining to unfair or deceptive practices are barred.

TWENTY-EIGHTH AFFIRMATIVE DEFENSE

With respect to each and every cause of action, Plaintiff is not entitled to recover because if the product involved was unsafe, which Merck denies, then it was unavoidably unsafe as defined in Restatement of Torts. The apparent benefits of the product exceeded any apparent risk given the scientific knowledge available when the product was marketed.

TWENTY-NINTH AFFIRMATIVE DEFENSE

Merck's advertisements and labeling with respect to the products which are the subject matter of this action were not false or misleading and, therefore, constitute protected commercial speech under the applicable provisions of the United States, Georgia, and New York Constitutions.

THIRTIETH AFFIRMATIVE DEFENSE

The public interest in the benefit and availability of the product which is the subject matter of this action precludes liability for risks, if any, resulting from any

activities undertaken by Defendant, which were unavoidable given the state of human knowledge at the time those activities were undertaken. With respect to Plaintiff's claims, if it is determined there is a risk inherent in the product which is the subject matter of this action, then such risk, if any, is outweighed by the benefit of the product.

THIRTY-FIRST AFFIRMATIVE DEFENSE

At all times relevant herein, any product which is the subject matter of this action manufactured and distributed by Merck in any state in the United States was manufactured and distributed in a reasonable and prudent manner based upon available medical and scientific knowledge and further was processed and distributed in accordance with and pursuant to all applicable regulations of the FDA.

THIRTY-SECOND AFFIRMATIVE DEFENSE

With respect to each and every purported cause of action, the acts of Merck were at all times done in good faith and without malice.

THIRTY-THIRD AFFIRMATIVE DEFENSE

To the extent there were any risks associated with the use of the product which is the subject matter of this action which Merck knew or should have known and which gave rise to a duty to warn, Merck at all times discharged such duty through appropriate and adequate warnings in accordance with federal and state law.

THIRTY-FOURTH AFFIRMATIVE DEFENSE

Plaintiff has not sustained an ascertainable loss of property or money.

THIRTY-FIFTH AFFIRMATIVE DEFENSE

Plaintiff has not suffered any actual injury or damages.

THIRTY-SIXTH AFFIRMATIVE DEFENSE

Plaintiff's claimed are barred under the doctrine of economic loss.

THIRTY-SEVENTH AFFIRMATIVE DEFENSE

This case is more appropriately brought in a different venue as defined in 28 U.S.C. §1404(a).

THIRTY-EIGHTH AFFIRMATIVE DEFENSE

This case is subject to dismissal and/or transfer to another venue pursuant to 28 U.S.C. §1406(a).

THIRTY-NINTH AFFIRMATIVE DEFENSE

This case is subject to dismissal or stay on the grounds of *forum non conveniens.*

FORTIETH AFFIRMATIVE DEFENSE

Plaintiff's claims of fraud are not pleaded with the required particularity.

FORTY-FIRST AFFIRMATIVE DEFENSE

Plaintiff cannot recover for the claims asserted because Plaintiff has failed to comply with the conditions precedent necessary to bring this action and/or each particular cause of action asserted by Plaintiff.

FORTY-SECOND AFFIRMATIVE DEFENSE

Plaintiff's claims for breach of warranty are barred because Plaintiff did not rely on such warranties and the claims are otherwise barred for lack of timely notice, lack of privity and/or because the alleged warranties were disclaimed.

FORTY-THIRD AFFIRMATIVE DEFENSE

An asymptomatic plaintiff lacks standing because she has suffered no damages and no injury-in-fact.

FORTY-FOURTH AFFIRMATIVE DEFENSE

To the extent that Plaintiffs assert claims based on Merck's adherence to and compliance with applicable state laws, regulations and rules, such claims are preempted by federal law under the Final Rule, Requirements on Content and Format of Labeling for Human Prescription Drug and Biologic Products, FDA Docket No. 2000N-1269 (January 24, 2006).

FORTY-FIFTH AFFIRMATIVE DEFENSE

The substantive law of Georgia applies to Plaintiff's claims.

FORTY-SIXTH AFFIRMATIVE DEFENSE

Merck avers that the Georgia statute respecting award of punitive damages, particularly O.C.G.A. § 51-12-5.1, subsection (e)(1) as contrasted to subsections (f) and (g) thereof, whereby no limitation is provided respecting actions involving products, but there is a limitation for other actions than products, violates the Constitution of the United States, particularly in that it affords products manufacturers, such as Merck, equal protection of the laws.

FORTY-SEVENTH AFFIRMATIVE DEFENSE

Pursuant to O.C.G.A. § 51-12-5.1, only one award of punitive damages may be recovered in the State of Georgia from Merck arising from product liability of a single product.

Inasmuch as the Complaint does not describe the alleged underlying claims with sufficient particularity to enable Merck to determine all of its legal, contractual and

equitable rights, Merck reserves the right to amend and/or supplement the averments of its Answer to assert any and all pertinent liability defenses ascertained through further investigation and discovery.

Merck will rely on all defenses that may become available during discovery or trial.

WHEREFORE, Merck respectfully demands judgment dismissing Plaintiff's Complaint with prejudice and awarding Merck such other and further relief that the Court may deem just and proper.

JURY DEMAND

Merck demands a trial by jury as to all issues so triable.

DATED: New York, New York
September 4, 2007

Respectfully submitted,

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By: /s/
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